JUN 2 9 2005

K051017

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510(k) Summary
R-X-Fix External Fixator

Date April 19, 2004

Submitter
R-X-Fix
3450 Highland Dr., #303
Salt Lake City, UT 84106

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade Name R-X-Fix External Fixator

Common name External fixator

Classification name appliance, fixation, nail/blade/plate combination, multiple component
Class II per 21 CFR section 888.3030

Product Code KTT

Equivalent Device Orthofix Dynamic Axial Fixation system (K955848)
Fixano Minifix Fixator (K964094)

Device Description
The R-X-Fix External Fixator is a stable solution for fractures and for lengthening of small bones. The R-X-Fix External Fixator is hinged to allow adjustment in horizontal or vertical axis and is used for comminuted intra-articular fractures, joint stiffness, or arthrodesis of the foot or hand. The hinge system allows range of motion at the joint during treatment. The design allows the placement of pins to be adjusted around three orthogonal axes and translated linearly.

Intended Use
The R-X-Fix External Fixator is indicated for stabilizing various fractures including open and/or comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies. The system allows precise, controlled compression/distraction and early weight bearing.

Non-clinical Testing
None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

R-X-Fix
C/o Mr. J.D. Webb
Orthomedix Group Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K051017
Trade/Device Name: R-X-Fix External Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: April 19, 2005
Received: April 21,2005

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: R-X-Fix External Fixator

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051017